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# IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:

YASUHIDE TACHI et al

Serial No. 024,111

Filed: March 26, 1979

For: NOVEL HYDROCORTISONE

Derivative

Examiner: Roberts

Art Unit: 125

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PETITION TO REVIVE ABANDONED ASST. COMM.
APPLICATION UNDER CFR 1.137

Honorable Commissioner of Patents and Trademarks Washington, D.C. 20231

Sir:

Applicants hereby petition through their undersigned attorney of record, that the above identified application be restored to the pending files and that abandonment be held to have been inadvertent and fortuitous and that the accompanying amendment be entered in this application and acted upon in due course. The circumstances outlined in the accompanying Attorney's Declaration and the Declaration of Rita M. Riley show that the late filing of the accompanying amendment was unavoidable. The Commissioner is further requested to take cognizance of the fact that it will work a great hardship upon Applicants to have to refile this application.

The facts and circumstances surroudning the accidental abandonment of this application are as follows:

The undersigned attorney, on June 16, 1979 opened a branch office, located at 542 So. 23rd Street, Arlington, Virginia, for the Boston firm of Kenway and Jenney. In due course the applications of his clients, including the above-captioned application, were docketed in three independent systems, i.e.

(1) docketing by his corretary on how dealest and and and

(2) docketing by himself on his own desk calendar and (3) docketing by the firm's docket clerk in Boston. The above-captioned application was docketed for a response due on October 29, 1979 (the 28th falling on a Sunday) in all three systems. However, due to events that were the fault of neither the applicants nor their attorney, all three systems failed in that the undersigned received no reminder of a response deadline during the period extending from October 16, 1979 to October 31, 1979 when the error was discovered by the undersigned.

No reminder whatsoever was furnished by the secretary's docket calendar due to a combination of a secretary's failure to follow directions and a changeover in secretarial personnel, as explained in detail in the accompanying declaration of the attorney.

As established by the accompanying declarations, no reminder was received from the Docket Clerk in Boston subsequent to October 16, 1979 notwithstanding at least one explicit request by the undersigned that reminders be given on the actual due dates and his understanding that his request would be honored.

As established by accompanying Declaration of the Attorney, the desk calendar of the undersigned, by virtue of an interleaf insert unique to one day out of the year, erroneously indicated to him that no response was due on October 29, 1979.

If not for obstinateness on the part of a secretary, if not for that secretary's failure to follow explicit directions, if not for the failure of the Boston Docket Clerk to honor my request for reminder on the day any response falls due, and if not for a peculiarity in the design of my desk calendar the response in question due the 29th of October would have been timely filed.

teachings of Elks et al <u>might</u> motivate the production of other halogen-substituted orthoester steroids, the teachings would in no way motivate production of the diester compound claimed here which is <u>not</u> halogen-substituted and has no orthoester ring. Shapiro et al, as its title indicates, is directed to 17-mono esters of corticoids. The <u>mono</u> esters of Shapiro et al, which like the compounds of Elks et al are halogen-substituted, are said to be superior to "their respective 17a-hydroxy analogs" (col 3, lines 53-55). The reference alleges <u>no</u> therapeutic effectiveness whatsoever for the halogen-substituted diesters (which are <u>not</u> mixed diesters) which are intermediates in the process.

The Elks et al and Shapiro et al secondary references relate only to halogen-substituted steroids and therefore one would not look to either secondary reference to solve the problem to which applicants' invention is directed, i.e. to provide a compound having at least comparable efficacy without the side-effects attributed to halogen substitution (see p.1, lines 15-18).

Based on the foregoing it is submitted that the references do not establish <u>prima</u> <u>facie</u> obviousness because:

- (1) none discloses any 17,21 diester of hydrocortisone;
- (2) none discloses a 17-butyrate, 21-propionate diester of any steroid; and
- (3) none recognizes the problems of ill side-effects attributed to halogen substitution; moreover, the two secondary references are directed solely to halogen-substituted compounds.

Assuming, arguendo, that the references somehow establish prima facie obviousness, it is submitted that the evidence of record consisting of the comparative tests reported at pages 4 and 5 of the present specification would serve to overcome the prima facie case. In this connection it should be noted that the data presents a comparison between the claimed compound and the closest prior art compound conceivably suggested by the prior art, i.e. hydrocortisone 17-valerate, 21-acetate (assuming, arguendo, that this latter compound is somehow suggested by the teaching of Ercoli et al, col 4, lines 43-52). Note that the claimed compound is shown to be 28% more potent as a vasoconstrictor than the 17-valerate, 21-acetate diester. Even greater superiority is seen when the potency of the claimed compound (2.47) is compared with that of its adjacent homologs, i.e. 17-butyrate-21-acetate (1.83) and 17-valerate-21-propionate (1.63).

While the prior art might lead one to expect that the choice of ester groups is, as stated by the Examiner, "nothing more than a matter of choice", the only data of record on this point evidences the opposite.

It is again requested that the two references cited in applicants' paper filed June 6, 1979 be considered and cited of record.

The Examiner is respectfully requested to reconsider the rejection in light of the foregoing with a view toward allowance of the sole remaining claim.

eorge

A.

Reg No. 25,814

Respectfully submitted

Date: November 2, 1979

KENWAY & JENNEY

542 So. 23rd Street

Arlington, Virginia 22202 Phone: (703) 979-1960 Dkt. No. TA/GL/A014

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# IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:

YASUHIDE TACHI et al

Serial No. 024,111

Filed: March 26, 1979

For: NOVEL HYDROCORTISONE
DERIVATIVE

DERIVATIVE

SEXAMINER: Roberts

Art Unit: 125

### DECLARATION OF ATTORNEY

Honorable Commissioner of Patents and Trademarks Washington, D.C. 20231

Sir:

- I, George A. Loud, hereby declare the following:
- 1. That, on June 15, 1979, I terminated my partnership with the firm of Lane, Aitken & Ziems and established a branch office for the firm of Kenway & Jenney at 542 South 23rd Street, Arlington, Virginia 22202. The principal office for the firm of Kenway & Jenney is located at Sixty State Street, Boston, Massachusetts;
- 2. That my file relating to this case reflects that an office action dated June 28, 1979 in connection with this case was received at the offices of my former firm, Lane, Aitken and Ziems on June 29, 1979 and that a copy of the office action together with a request for instructions for a response thereto was promptly forwarded to the applicants on July 10, 1979; and that the file further reflects that pursuant to applicants' telex request, an extention of time up to and including October 28, 1979 was obtained on September 21, 1979.

- 3. That, the new response deadline on October 28, 1979 was docketed on three docket calendars; more specifically, the October 28 response date was docketed on both the attorney's calendar (Attachment B2) and on his secretary's calendar (Attachment A); moreover, the docket clerk at the principal office of Kenway & Jenney, located at Sixty State Street, Boston, Massachusetts, was notified of the new deadline; that, as will be seen below, all three docket systems failed;
- 4. That a secretary with extensive patent experience was hired for the Arlington office effective June 12, 1979;
- 5. That on June 16 or within several days thereafter all applications for which I had responsibility were docketed with entries for response deadlines being made both by the secretary on her docket calendar and by myself on my "Style 017 Success" desk calendar and that, as new deadlines were created and old deadlines were reset, new entries were made on each of the two calendars;
- 6. That the secretary hired for the new office at that time continued in employment through October 9, 1979, on which date her employment terminated; that, as was the practice at the firm with which she was previously associated, she docketed all response on her calendar two weeks in advance of their due date; that on a number of occasions I demanded that she also docket responses on the date due; that for reasons of her own she resisted any changes in the procedures to which she had become accustomed; that this refusal to follow instructions, in this and in other matters, led to the termination of her employment on October 9, 1979.

- 7. That, as of the secretary's termination on October 9, 1979, I thought that she was in compliance with my instructions regarding docketing; however, my careful review on October 31, of the secretary's docket calendar reveals that some deadlines were docketed on the date the response fell due and other deadlines were docketed only for reminder two weeks in advance of the actual due date;
- 8. That Attachment A hereto is a true copy of the secretary's docket calendar for the month of October and shows an entry for U.S. Application Serial No. 024,111 on October 14, 1979, two weeks in advance of the due date on October 28, and that no entry was made for October 28;
- 9. That I employed a temporary secretary (a "Kelly Girl") during the period spanning October 10 through October 12, 1979 and that a new permanent secretary started work on October 16, 1979 and continues in that position as of this date;
- 10. That, on her first date at work the new permanent secretary was instructed to check her docket calendar as her first item of business every morning; however, due to the lack of any entry for a response in USSN 24,111 subsequent to her date of employment I did not receive any reminder from her that a response was due on October 28;
- 11. That, through the succession of secretaries, I never received any reminder from any secretary of the response due in USSN 024,111 on October 29th (the 28th fell on a Sunday); that, in fact, I had no secretary from October 12 until October 16, 1979, which period encompasses the only entry on the secretary's calendar for the month of October, pertaining to USSN 024,111;

- 12. That I have no recollection as to who or why the entry for October 14, 1979 was crossed out on the secretary's docket calendar;
- 13. That on October 16, I received a telephone call from the docket clerk in our Boston Office to remind me of responses due during the month of October at which time she specifically reminded me of the responses due in USSN 024,111 on October 29, 1979; however, as of the 16th I had not yet received instructions for a response; those instructions were not received until October 25, 1979; that, on at least one previous occasion I had asked the docket clerk in Boston to telephone me on the day a response is due to remind me of that deadline; that, to the best of my recollection, on October 16, 1979 I repeated that request asking for a follow-up reminder on the only two deadlines remaining on my docket for the month of October, of which the October 29th deadline in USSN 024,111 was one; that, in any event, I expected a follow-up call on October 29; that the other response deadline falling in October after the 16th was extended several days in advance and a copy of the extension mailed to the docket clerk in Boston;
- on which the respone in question was actually due (the 28th falling on a Sunday) I flipped my desk calendar to that date and saw a blank page (Attachment Bl) for that date indicating to me that no response was due on the 29th; unfortunately, the desk calendar is of a type having two pages for each date and the other page for Monday the 29th was obscured by page entitled "1980 Order Blank" included in the calendar for the purpose of reminding one to order a 1980 refill; had the "1980 Order Blank" page been turned it would have revealed a reminder of the response (see Attachment B2), but it was not:

- 15. That, on October 29, 1979, unaware that the response was due that day, a draft of the response was completed and given to the new permanent secretary for typing and that it was not typed until October 31, due to a typing backlog;
- 16. That, on October 31, 1979, I reviewed the material awaiting typing to determine their priority and discovered that the response in question should have been filed on October 29;
- 17. That I have instructed my new permanent secretary to docket all responses for the date due; and have obtained agreement with the responsible personnel in our Boston office that I will be provided with a reminder by telephone on any day any respone or other action falls due;

18. That I further declare that the foregoing statements are based upon my personal knowledge and information of the facts; and further that these statements are made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issuing thereon.

Reg. No. 25,814

Date: Nov 2, 1979

KENWAY & JENNEY 542 South 23rd Street Arlington, Virginia 22202

(703) 979-1960

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# IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Th re Application of:

YASUHIDE TACHI et al

Serial No. 024,111

Filed: March 26, 1979

For: NOVEL HYDROCORTISONE

DECLARATION OF RITA M. RILEY

Honorable Commissioner of Patents and Trademarks Washington, D.C. 20231

DERIVATIVE

Sir:

- I, RITA M. RILEY, hereby declare:
- ${\tt 1.\ That\ I\ am\ a\ citizen\ of\ the\ United\ States,\ residing}$  at 175 Quincy Shore Dr., North Quincy, Massachusetts.
- 2. That I am employed by the firm of Kenway & Jenney at their office located at 60 State Street, Boston, Massachusetts 02109 and that I am chief docket clerk for the firm;
- 3. That, subsequent to the opening of our firm's branch office at 542 So. 23rd St., Arlington, Va., I had several discussions with the secretary at the branch office and a somewhat lengthy conversation (sometime during the month of September 1979) with the attorney in charge of the branch office, George A. Loud, pertaining to integration of the branch office docketing with the docketing at our Boston office;
- 4. That, during said September conversation with Mr. Loud, he requested that he be notified by telephone the day a response was due;

- 5. That, subsequent to said September conversation, I discussed the docketing procedure for our Arlington office with Robert J. Lettich, office manager for our firm; that Mr. Lettich and myself decided that calls to the Arlington office on days that responses in cases on Mr. Loud's docket fell due would amount to an unnecessary burden in view of the docketing procedure already established at the Arlington office and that monthly telephone calls would be sufficient: and that the procedure decided upon was not discussed with Mr. Loud;
- 6. That on October 16, 1979 I spoke with Mr. Loud by telephone, at which time I reviewed his docket and reminded him that a response was due October 28, 1979 in the application of YASUHIDE TACHI et al U.S. Serial No. 024,111, filed March 26, 1979, and that, prior to October 31, 1979, I gave Mr. Loud no further reminder pertaining to said application;
- 7. That, I have no recollection that, during our telephone call on October 16, 1979, Mr. Loud requested a follow-up call on the due date for a response in said application;
- 8. That, on October 31, 1979, Mr. Loud telephoned to inform me that the response due in said application on October 29, 1979 had not yet been filed;
- 9. That, as a result of the inadvertent failure to file a response in said application on October 29, our procedure in the Boston office relative to the docketing of Mr. Loud's cases has been changed to give telephone reminders directly to Mr. Loud on any date a response falls due; and

10. That, I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application of any patent issuing thereon.

Gita On. Giley
RITA M. RILEY

Date: November 1, 1979